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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
HINES, JANA A	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 08/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/795,873	HERMET ET AL.	
	Examiner	Art Unit	
	Ja-Na Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *August 8, 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) *11-12,18-22 and 29-36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,13-17 and 23-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/8/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I in the reply filed on August 8, 2006 is acknowledged. Claims 29-36 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Claims 11, 12 and 18-22 have been withdrawn in view of applicants' election of species. Therefore claims 1-10, 13-17 and 23-28 are under consideration in this office action.

Specification

2. The use of the trademark TRITON™, TWEEN™ and other reagents have been noted in this application on at least page 9. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Drawings

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: Figure 12 and reference numbers 1-8 are not described in the specification. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the

specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-10, 13-17 and 23-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) Claim 1 step e) refers to a marker agent while step f) refers to detecting labeled microbes. It is unclear how the microbes become labeled, i.e., if the marker agent labeled the microbes or if there is another labeling means. Therefore clarification is required to overcome the rejection.

b) The claim scope of claims 4 and 23 is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A

trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a particular material, i.e. detergents and accordingly, the identification is indefinite. Furthermore, the use of trademarks is improper since products identified by trademarks are within the sole control of the trademark owner and are subject to change by said owner at their discretion.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-5, 8, 10, 14-16 and 23-28 are rejected under 35 U.S.C. 103(a) as being unpatentable Doshi et al., (US Patent 5,766,552) over in view of Schrenk et al., (US Patent 5,316,731).

The claims are drawn to a method for detecting contaminating microbes possibly present in a blood product comprising blood cells comprising: a) subjecting a sample of the blood product to an aggregation treatment of the blood cells, b) substantially eliminating aggregates formed in step (a) by passage of the sample over a first filter allowing passage of contaminating microbes, but cell aggregates, c) selectively lysing residual cells of the filtrate obtained in step (b), d) recovering the contaminating

microbes by passage of the lysate from step (c) over a second filter allowing passage of cellular debris, e) adding a marker agent of the contaminating microbes either during step (a) or step (c), and f) analyzing material on the second filter to detect labeled contaminating microbes possibly retained by the second filter. The dependant claims are drawn to permeabilization agents, detergents, marker agents, blood products, antibodies, lectins, the filters and the device.

Doshi et al., teach that the separation of serum or plasma from whole blood is extremely important since it is difficult to conduct the analysis of dissolved blood components without interference from red blood cells (col. 1, lines 47-50). Red blood cells (RBC) can be removed from whole blood samples by contacting a whole blood sample with an agglutinating agent (col. 7, lines 25-28). The agglutinating agents allow for the quick and efficient formation of clusters of RBC, just as required by the claims (col. 5, lines 32-34). By contacting the RBC with agglutinating agent, the cells are agglutinated and trapped by the pad while the remainder of the fluid sample flows through readily (col. 6, lines 10-15). Doshi et al., also teach the efficiency of filtration, along with the lysis of RBC wherein whole blood is passed through the filter and plasma is retained (col. 8, lines 54-56). Also taught is the removal of the RBC clusters by filtration (col. 11, lines 40-41). The preferred filtration uses a porous absorbent pad with mesh or pore size being from about 20 to about 500 microns (col. 62-65). This is within the instantly claimed size of pores for the first filter. The secondary filter should have a very small pore size to permit plasma to pass and ideally has a pore size between 1and 5 microns (col. 12, lines 1-11). Doshi et al., also teach having a reactant pad through

which the fluid flows to allow for the production of a detectable signal (col. 14, lines 39-41). The analyte reacts with the reagents to produce a detectable signal (col. 14, lines 42-43). Thus, where the analyte is an enzyme substrate, the pad may be impregnated with the appropriate enzyme or enzymes to produce a product which can then be measured (col. 15, lines 10-13). The method also teaches a measurement dye zone wherein the zone is coated or impregnated with an indicator material that reacts with the enzyme treated sample to give an indication of the presence or amount of analyte in the sample (col. 16, lines 23-27). Thus the indicator material is equivalent to the instantly claimed marker agent.

One type of RBC agglutinating agent is lectins, including *Phaseolous vulgaris* (col. 7, lines 46-48). Other agglutinating agents include antibodies that have a binding affinity for a determinant present on the surface of red blood cells which can recognize antigenic surface constituents (col. 7-8, lines 65-8). There is generally a minimum amount of antibody that must be used in the blood separation device (col. 8, lines 43-45). Doshi et al., states that one skilled in the art can readily determine the optimum amount of antibody to be used in the method (col. 8, lines 49-51). Thus the art teaching using an appropriate concentration of antibody, just as instantly claimed. Also taught are the uses of detergents where a lipophilic analyte is in the blood (col. 15, lines 27-28). The detergents can be nonionic, anionic or cationic detergents (col. 15, lines 33). Thus the art teaches using cationic and anionic detergents, just as instantly claimed. Doshi et al., teach using various sticking agents or adhesives (col. 15, lines 38-41). These

sticking agents are equivalent to the permeabilization agents instantly claimed. However, Doshi et al., do not teach selectively lysing residual cells of the filtrate.

Schrenk et al., teach the collection and processing of biological samples, such as blood and serum (col. 1, lines 5-7). Schrenk et al., teach a method wherein the container is useful for testing for microbial contamination (col. 3, lines 10-13). The art teaches the use of filters as a separation means (col. 2, lines 54-68). The inner chamber contains a reagent which lyses red and white blood cells but not microbial contaminants (col. 3, lines 16-18). Examples of useful reagents include saponin and ethylenediamine tetraacetate acid (EDTA) (col. 3, lines 22-23). Therefore, once the blood has been contacted with the reagent it is analogous to a concentrate and then may be subjected to testing for microbial contamination (col. 3, lines 47-50). Schrenk et al., teach that an advantage is the ability to provide a concentrate of fluid which contains cellular debris and contaminating microbes without subjecting the blood sample to time consuming and expensive centrifugation techniques (col. 5-6, lines 65-3).

Therefore, it would have been prima facie obvious at the time of applicants' invention to modify the method of Doshi et al., to include a lysis step as taught by Schrenk et al. No more than routine skill would have been necessary to include a lysis step in the method of detection, since the art teaches that it is desirable to rid a blood sample of substantially all blood cells since it is difficult to conduct the analysis of dissolved blood components without interference from those red blood cells. Moreover, there would have been a reasonable expectation of success in this modification since

the art teaches that the lysis step does not harm the contaminants yet simultaneously prepares the blood sample for microbial detection and analysis.

6. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable Doshi et al., (US Patent 5,766,552) and Schrenk et al., (US Patent 5,316,731) further in view of Cathey et al., (US Patent 5,798,215).

The claims are drawn to a method for detecting contaminating microbes comprising a marker agent that comprises a fluorescent marker or an agent coupled to a flurochrome or an enzyme enabling degradation of substrate thereby made fluorescent wherein the fluorescence is detected by an excitation laser. Doshi et al., and Schrenk et al., have been discussed above however neither teaches the instantly claimed marker agent.

Cathey et al., teach analyte detection assays wherein the assay platform comprises a filter (col. 6, lines 19-21). The separation means for separating sample components may be positioned in the flow path of the assay platform (col.6, lines 54-56). For example, a filter may be positioned in the waste area prior to the vent so that in assays of samples comprising red blood cells, the red blood cells are retained in the waste area while serum flows through the filter (col. 6, lines 56-60). Depending upon the nature of the sample, the sample may be subjected to prior treatment, such as filtration or cell separation (col. 12, lines 15-19). For blood, one may wish to remove red blood cells to provide plasma or serum (col. 12, lines 20-21). Upon addition to the liquid addition port, the substrate is hydrated and then flows into the main flow path, where it

is converted by an enzyme to a detectable product (col. 14, lines 34-36). Thus, the fluorescent labels or enzymes can convert substrates to non-diffusible dyes can be used in signal producing systems (col. 13, lines 60-64). Optical signals which may be detected and related to the presence and/or amount of analyte in the sample include emissions, e.g. from fluorescent labels or the fluorescence of a quenching member of a signal producing system (col. 14, lines 53-56).

Therefore, it would have been prima facie obvious at the time of applicants' invention to modify the method of Doshi et al., and Schrenk et al., to include a marker agent that comprises a fluorescent marker or an enzyme enabling degradation of substrate thereby made fluorescent wherein the fluorescence is detected by an excitation laser as taught by Cathey et al. No more than routine skill would have been necessary to include this marker agent in the method of detection, since the art teaches that it is desirable to use fluorescence detection signals to detect analytes and other microbes. Moreover, there would have been a reasonable expectation of success in this modification since only routine skill would have been required to use an alternate yet functionally equivalent detection system that detects microbes found in blood samples.

7. Claims 9 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Doshi et al., (US Patent 5,766,552) and Schrenk et al., (US Patent 5,316,731) further in view of Besson-Faure et al. (US Patent 6,168,925).

The claims are drawn to a method for detecting contaminating microbes comprising a specific antibody to a platelet antigen such as anti-GpIIb/IIIa. Doshi et al.,

and Schrenk et al., have been discussed above however neither teaches a specific antibody to a platelet antigen such as anti-GpIIb/IIIa.

Besson-Faure et al., teach the analysis of platelet GpIIb/IIIa receptors (col. 1, lines 5-8). Activated platelets have this receptor which binds with very high affinity and causes aggregation of the platelets with each other (col. 1, lines 25-30). Besson-Faure et al., also teach anti-GpIIb/IIIa antibodies which are publicly available (col. 3, lines 1-10). Thus, Besson-Faure et al., teach the anti-GpIIb/IIIa antibody as a specific antibody to a platelet antigen, just as required by the claim.

Therefore, it would have been prima facie obvious at the time of applicants' invention to modify the method of Doshi et al., and Schrenk et al., to include the anti-GpIIb/IIIa antibody as a specific antibody to a platelet antigen as taught by Besson-Faure et al. No more than routine skill would have been necessary to include this antibody in the method of detection, since the art teaches that it is desirable to use antibody agglutinating agents that have a binding affinity for a determinant present on the surface of red blood cells and which can recognize antigenic surface constituents. Moreover, there would have been a reasonable expectation of success in this modification since only routine skill would have been required to use an alternate yet functionally equivalent antibody that recognizes a platelet antigen and causes aggregation of the platelets with each other.

Prior Art

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Blatt et al., (US Patent 5,981,294) teach an invention wherein there is a filter for separating red blood cells from a whole blood sample. Kirkham et al., (US Patent 3,635,798) teach a method for detecting contaminating microbes comprising an aggregation treatment which substantially eliminating the aggregates, passage of the sample over a first filter and second filter, adding a marker agent and analyzing material on the second filter. Schulte (US Patent 4,717,660) teach the detection of bacteria by fluorescence.

Conclusion

9. No claims allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines
July 12, 2006

ROBERT A. ZEMAN
PRIMARY EXAMINER